

REMARKS

The present application relates to inbred maize plant and seed PH94T. Claims 1-10 are pending in the present application. Claim 2 has been amended in the present response. New claims 11 and 12 have been added. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

The specification is objected to by the Examiner for the "embedded hyperlink and/or other form of browser-executable code". Applicant has now amended the specification on page 69, to remove the hyperlink and instead just recite the Internet address as in accordance with MPEP § 608.01, thereby alleviating this objection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2-3 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states claim 2 is indefinite because "the F1 hybrid maize seed lacks antecedent basis in claim 1". The Examiner also includes dependent claim 3 in the rejection.

Applicant has now amended claim 2 to include proper antecedent basis, thus alleviating this rejection to claims 2-3.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-10 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the Applicant "describes inbred maize line PH94T having specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines". The Examiner goes on to acknowledge that the

Applicant has described "a single F1 hybrid seed/plant of PH94T". The Examiner then states "it is unclear if the seed of said F1 hybrid of the inbred PH94T have been deposited and is publicly available. These are genus claims".

Applicant traverses this rejection. Applicant has satisfied the written description requirement by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH94T, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants and by the description of the SSR marker profile in Table 4 of the specification. (*See* specification, p. 70-73).

The Examiner further states that *Eli Lilly* stands for the proposition that it "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Further, the Examiner cites that "the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of species of the claimed genus, and that one of ordinary skill in the art should be able to 'visualize or recognize the identity of members of the genus'". *Id.* (Office Action, p. 3-4).

Applicant submits that in accordance with the *Eli Lilly* standard recited by the Examiner, the genus of F1 hybrids encompassed by Applicant's claims 1-12 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with PH94T from an F1 hybrid not made with PH94T. This is because cells and/or chromosomes of inbred line PH94T provide an identifying structural feature possessed by all members of the claimed genus. (Specification, p. 70-73). In addition, new claims 11 and 12 were added to further characterize the claimed invention. Therefore, since Applicant has deposited the seed of inbred maize PH94T and provided the marker profile in Table 4, thereby allowing one skilled in the art to identify the F1 hybrids in relation to the structural feature of the claimed invention, the written description requirement of 35 U.S.C. § 112, first paragraph has been met.

The Examiner states "Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds produced by crossing the inbred maize line PH94T with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish the claimed hybrid corn plants/seeds from other corn plants and seeds are described. The only description recited in the claims is that the hybrid comprises at

least one set of chromosomes from inbred PH94T. However this description is insufficient to provide distinguishing characteristics, given that all hybrids comprise at least one set of chromosomes from one of its parents. In addition, the set of chromosomes are unknown".

Applicant respectfully traverses this rejection. Most importantly Applicant points out that the SSR profile has been described in the present application and the Examiner's assertion that the "set of chromosomes is unknown" is improper. (Specification, p. 70-73). Further, Applicants may fulfill the written description requirement of § 112, first paragraph by depositing material in a public depository, where the deposited material is not accessible in writing, and where reference to the deposit is made in the specification. *Enzo Biochem, Inc.*, 323 F.3d at 965, 63 U.S.P.Q.2d at 1613. Applicant deposited representative seed of inbred line PH94T with the ATCC as deposit number PTA-4692. This deposit contributes to the written description of inbred maize line PH94T of claims 1, 4 and 7 and to the written description of a maize plant, and its parts, grown from PH94T of claims 2-3, 5-6 and 8-10 and newly submitted claims 11 and 12. Likewise, this deposit also contributes to the written description of the F1 hybrid seed and plants claims 1-10 because it provides the cells and/or chromosomes referenced in the specification (p. 76). Applicant also asserts the SSR marker profile provided in Table 4 of the specification and new claims 11 and 12 which reference Table 4 also contribute to the written description of the F1 hybrid seed and plants of claims 1-10. It is vital to conceptually understand that the an F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics may be exemplified by the SSR profile present in both the inbred and the F1 hybrid. (*See* specification, p. 70-73). Thus Applicant respectfully submits the claimed invention is in accordance with the written description guidelines.

In addition, Applicant submits that there is an overall misunderstanding of the relationship between the claimed inbred and F1 hybrids. For example, the Examiner states the F1 hybrid generated will comprise millions of different possible genetic combinations and will be unpredictable but Applicant asserts this is only true in a segregating population. (Office Action, p. 5). However, an F1 hybrid is not a segregating population and the commercial hybrid industry is based on the fact that a F1 hybrid is genetically stable and consistently reproducible. It is well known to one ordinarily skilled in the art that a hybrid made from an inbred will receive one set of chromosomes from that inbred parent. This is because the genome of a maize inbred

line is homozygous. This homozygosity is a consequence of self pollination that occurs during the inbreeding process. As described in the PH94T specification,

The inbred has been self-pollinated and ear-rowed a sufficient number of generations with careful attention paid to uniformity of plant type to ensure the *homozygosity* and phenotypic stability necessary to use in commercial production. The line has been increased both by hand and in isolated fields with continued observation for uniformity. No variant traits have been observed or are expected in PH94T. (Specification, p. 26, lines 19-24, emphasis added).

Exhibit 1, submitted herewith, is a visual representation of the fact that most of the cells in a corn inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes the ten chromosomes are represented by three rectangles in the Exhibits).

When the inbred is used to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells will receive one of the inbred's sets of chromosomes.

As known to one of ordinary skill in the art and as shown in Exhibits 2 and 3, attached herewith, when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. Therefore, the genus of F1 hybrid seed and plants encompassed by Applicant's claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH94T. Stated in patent terms, it can be said that an F1 hybrid made with PH94T *comprises* the unique chromosomes of inbred PH94T. This unique set of chromosomes can be described by molecular markers which can be characterized by molecular marker methods known to those of skill in the art. (Specification, p. 7 and 70-73). This unique set of chromosomes is described in the SSR profile in the specification on pages 70-73 (Table 4).

Applicant emphasizes that essentially no variation is expected by one ordinarily skilled in the art in the hybrid genome as described by the morphological and genotypic characteristics discussed *supra*. Applicant points out that the intention of the production of hybrids is to retain the homozygosity of the inbred maize lines as stated in the specification; "[i]nbred maize lines are typically developed for use in the production of hybrid maize lines. Inbred maize lines need to be highly homogeneous, substantially homozygous and reproducible to be useful as parents of commercial hybrids. There are many analytical methods available to determine the homozygotic

stability and the identity of these inbred lines" as discussed *supra*. (Specification, page 24, lines 23-26).

Therefore, the Examiner's assertions are respectfully incorrect because in the present invention the genomic structure of PH94T is not different from hybrid to hybrid due to the highly homogenous nature of inbred maize lines. These characteristics are known facts to one of ordinary skill in the art of inbred maize lines and are sufficient to provide the distinguishing characteristics necessary to comply with 35 U.S.C. § 112, first paragraph.

On page 4 of the Office Action, the Examiner states "[f]urthermore, variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-PH94T parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-PH94T inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ".

Applicant traverses this argument. Applicant has complied with the written description standard by a reduction to practice and description of sufficient identifiable characteristics of the claimed F1 hybrid seed and plants produced from maize inbred line PH94T. However, the Examiner is creating a standard of written description that exceeds that required by law. The Applicant has provided "distinguishing characteristics" of the claimed genus as stated by the Examiner in the present Office Action (p. 4). As explained above, these specific identifying characteristics are the cells and/or chromosomes of PH94T described in the deposit of the present application and present in the claimed F1 hybrid genus. The cells and/or chromosomes are present in the genus of F1 hybrids made with PH94T and absent in the genus of F1 hybrids not made with PH94T. To require Applicant to further describe aspects of the claimed invention that are not the point of patentability of the genus extends the written description requirement beyond the legal standard.

According to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the

genus that distinguish them from others." The unique set of chromosomes developed by Applicant and genetically fixed in inbred maize line PH94T is an identifying structural characteristic present in both Applicant's seed deposit of PH94T, the SSR profile of PH94T in Table 4 of the specification and the genus of F1 hybrid seed and plants produced with PH94T.

The Examiner goes on to suggest that "while the technology of corn breeding is mature and the level of skill of a corn breeder is relatively high, a plant breeder cannot predictably determine the identity (morphological or physiological characteristics) of a progeny even when both parents involved in the breeding are known/described. Applicants own specification provides evidence for this unpredictability. At page 2, paragraph 8 of the specification '[T]he breeder can theoretically generate billions of different genetic combinations via crossing, selfing and mutations. The breeder has no direct control at the cellular level. Therefore, two breeders will never develop the same line, or even similar lines, having the same corn traits'. The specification also states 'The inbred lines which are developed are unpredictable. This unpredictability is because the breeder's selection occurs in unique environments, with no control at the DNA level (using conventional breeding procedures), and with millions of different possible genetic combinations being generated. A breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion. The same breeder cannot produce the same line twice by using the exact same original parents and the same selection technique'". (Office Action, pages 4-5).

Applicant respectfully traverses this argument. Applicant again points out that an F1 hybrid is to a segregating population. Applicant asserts that this statement by the Examiner is not relevant because it does not refer to an F1 hybrid as is claimed in the present application. In contrast, it is described in the specification how an important consequence of the homozygosity and homogeneity of an inbred line is that it can be used to consistently reproduce an F1 hybrid made with that inbred. (Specification, page 8, lines 26-30). The claimed F1 hybrids of the present application are based on a stable inbred line where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH94T, as may be further exemplified by the SSR profile. (Specification, p. 70-73). As the Examiner notes, the technology of corn breeding is mature and the level of skill of a corn breeder is relatively high. Since corn breeders have been consistently using inbreds to produce F1 hybrids for the better

part of the last century, it is difficult for Applicant to understand how the production of the claimed F1 hybrids could be considered unpredictable.

Applicant would like to reiterate that according to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." In the claimed invention, the unique set of chromosomes of inbred maize line PH94T, further described in the SSR profile of Table 4, is a further identifying structural characteristic present in both Applicant's seed deposit of PH94T and the genus of F1 hybrid seed and plants produced with PH94T. A genus of F1 hybrids may now be produced because Applicant has invented PH94T, and Applicant should be entitled to claims encompassing this genus.

Applicant would also like to note that the Examiner does not specify how the rejection under 35 U.S.C. § 112, first paragraph, applies to claims 7-10. Applicant asserts that claims 7-10 are adequately described according to the written description guidelines by virtue of the inbred plant cell being on deposit as discussed *infra* and thereby can be obtained from the seed of inbred maize line PH94T. One of ordinary skill in the art would know that the pericarp tissue is genetically identical to the maternal parent. It is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. The pericarp tissue that surrounds the seed is 2n maternal tissue only, the embryo is 2n tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is 3n tissue resulting from the fusion of two maternal and one paternal gametes. Hence, the seed of maize has been described as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel. Therefore, Applicant points out that intact cells from inbred PH94T will be a component of the F1 hybrid seed produced with PH94T as the maternal parent. Further, the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH94T and can be characterized by molecular markers. (For example, *see* specification, p. 70-73).

Moreover, Applicant has described how to produce an F1 hybrid from inbred maize line PH94T. (Specification, p. 8, lines 9-24). By virtue of the deposit of representative seed of line PH94T, an individual would be able to grow a maize plant, and its parts, from PH94T seed. It would be routine to cross this plant with another to produce F1 hybrid seed. The marker profile of Table 4 also provides identifying characteristics in conjunction with new claims 11 and 12 that reference Table 4, which adequately identify the structural features of the hybrids claimed along with the deposit that has been made. A person skilled in the art would thus recognize that Applicant was in possession of F1 hybrid maize plants produced from PH94T. Accordingly, claims 1-12 are adequately described by the specification.

The Examiner concludes by stating "[g]iven this unpredictability in the art; the vast number of hybrids encompassed by the claims; the substantial variation in phenotypes expected among these hybrids; the vast number of unidentified non-PH94T involved in the breeding, the disclosure of a single hybrid of the inbred PH94T will not provide adequate written description for all F1 hybrids". (Office Action, p. 5).

Applicants traverse this argument. As stated above, the essential test of written description is whether Applicant has demonstrated possession of a claimed invention such that one skilled in the relevant art would recognize that the Applicant was the inventors of the invention as claimed. Applicant has taught that the main utility of an inbred line is to produce F1 hybrid seed and plants and the production of these F1 hybrid seed and plants are predictable. (See Specification, page 31, lines 1-10). Applicant has made a deposit of inbred PH94T that fully enables others to make the genus of F1 hybrid seed and plants of claims 1-12. The genus of F1 hybrids encompassed by Applicant's claims comply with the written description requirement for the reasons explained *supra*. One skilled in the art would thus recognize that Applicant was in possession of F1 hybrid seed and plants produced from line PH94T as of the filing date of the application.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Summary

Applicant submits there has been adequate written description of the claimed F1 hybrid genus. The genus of F1 hybrids encompassed by Applicant's claims 1-12 are described in relation to the cells and/or chromosomes of inbred line PH94T, which provide an identifying structural feature possessed by all members of the claimed genus. Specifically, the genus of F1 hybrid seed and plants encompassed by Applicant's claims all share the common structural attribute of having a complete set of the chromosomes of PH94T, and a description of the set of chromosomes is disclosed in Table 4 of the present application. In addition, the SSR profile of PH94T is obtainable from the deposit of PH94T by one of ordinary skill in the art, utilizing SSR markers publicly known at the time of filing this application. In addition, the F1 hybrid seed also will comprise an intact cell from inbred maize line PH94T when PH94T is the maternal parent. Therefore, one of ordinary skill in the art would thus recognize that Applicants were in possession of F1 hybrid maize seed and plants produced from PH94T. Applicant has fully satisfied the legal standards for written description as set forth in case law and the written description guidelines.

Applicant further acknowledges that claims 1-10 are deemed free of the prior art. The Examiner further states the prior art fails to teach or suggest a hybrid maize seed/plant produced from the inbred maize PH94T, wherein the hybrid comprises at least one set of chromosomes of inbred PH94T. Applicant thanks the Examiner for recognizing that prior art hybrids do not comprise one set of chromosomes of inbred PH94T.

Conclusion

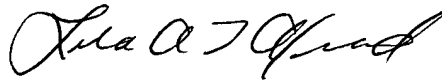
In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Please consider this a two month extension of time from February 19, 2005 to April 19, 2005, under the provision of 37 C.F.R. § 1.136(a) and charge Deposit Account No. 26-0084 for the amount of \$450.00. No other fees or extensions of time are believed to be due in connection

with this amendment; however, consider this a request for any fees inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

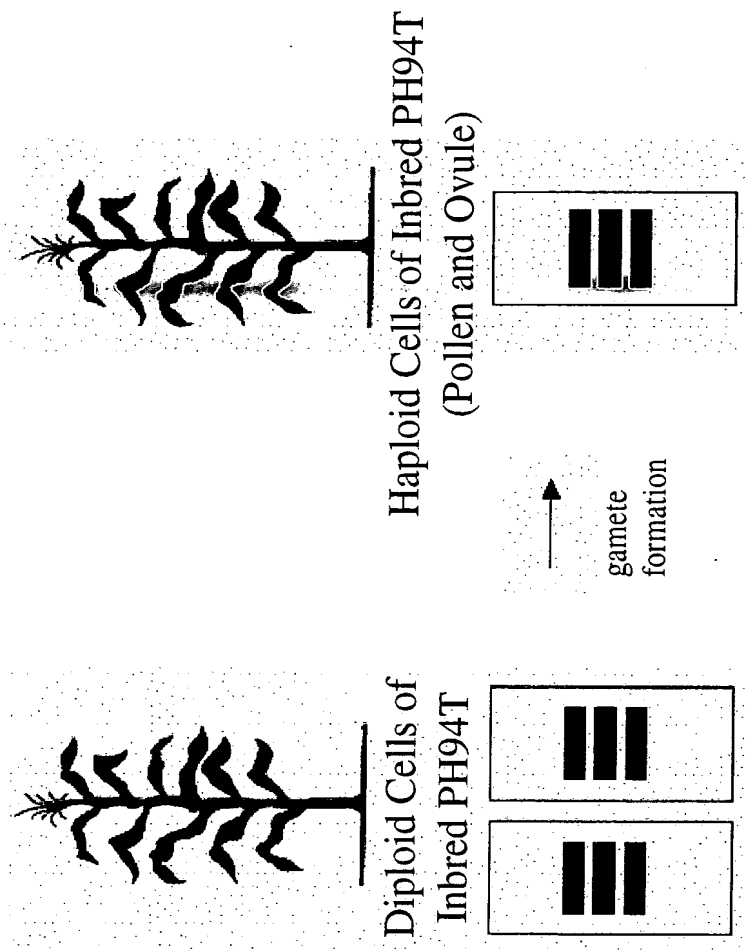
A handwritten signature in cursive script, appearing to read "Lila A. T. Akrad".

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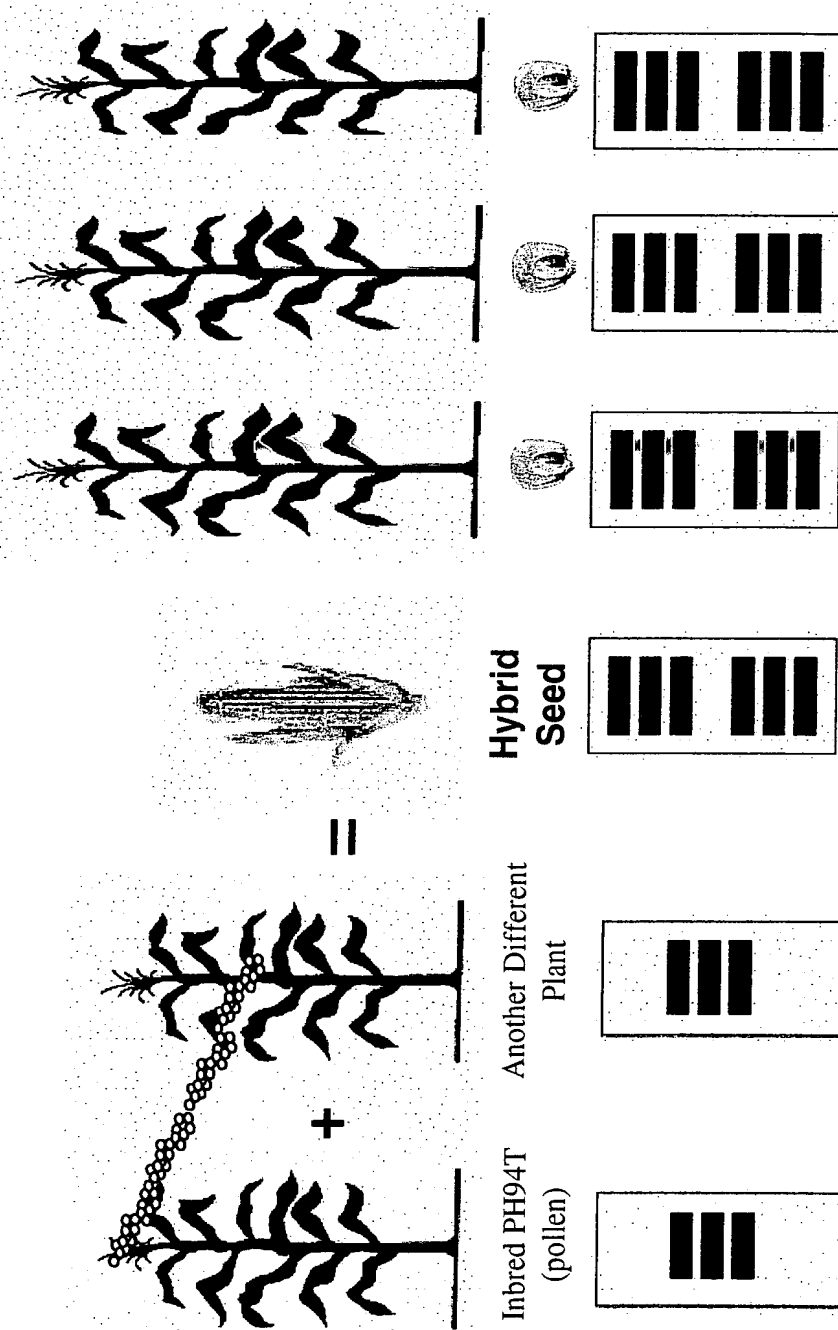
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Attorneys of Record

Chromosomal View of Inbred PH94T



F1 Hybrid corn seed and plants: PH94T as Male Parent



F1 Hybrid corn seed and plants: PH94T as Female Parent

